REMARKS

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-68 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled. This rejection is respectfully traversed.

As a preliminary matter, applicants would like to state for the record that while the Examiner's 112-first rejection is characterized as a written description rejection, the Examiner's use of the *Wands* factors in the analysis of the rejection indicates that the Examiner's rejection is in fact an enablement rejection and not a written description rejection. In view of the foregoing, applicants are addressing the Examiner's rejection as an enablement rejection.

35 U.S.C. § 112, first paragraph, reads as follows:

> *The specification shall* contain a written description of the invention, *and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same,* and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The purpose of the enablement requirement is to assure that inventors provide sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the specification and the knowledge in the art. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1896 (Fed. Cir. 1991). The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 20 USPQ2d 1300 (Fed. Cir. 1991). The Federal Circuit has explained that the question of undue experimentation is not a single, simple factual determination, but rather, it is a conclusion that is reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) (The key word is "undue," not "experimentation.").

In *In re Wands*, the Federal Circuit set forth eight factors to consider when determining whether a disclosure would require undue experimentation, they are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. The Federal Circuit has, on more than one occasion, cautioned that the *Wands* factors are illustrative and not mandatory and that all of the factors need not be reviewed when determining whether a disclosure is enabling. *Enzo Biochem., Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999), citing, *Amgen, Inc. v. Chugai*

Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), *cert. denied,* 502 U.S. 856 (1989).

Applying some of the *Wands* factors, i.e., presumably only those that the Examiner finds relevant, the Examiner takes the position that the claimed invention is not enabled by the disclosure. The following discussion will demonstrate the flaws in the Examiner's *Wands* factor analysis and why the claimed invention is legally enabling. The Examiner's *Wands* factor analysis sets forth five of the eight *Wands* factors. For purposes of clarity, the *Wands* factors are discussed in the order presented by the Examiner in the Office Action under reply.

THE NATURE OF THE INVENTION

The Examiner characterizes the nature of the invention as including any or a wide representation of soft and hard tissue capable of being treated by the claimed method (Office Action, page 3). Applicants submit that the Examiner's characterization of the nature of the invention is not accurate because contrary to the Examiner's assertion, the nature of the invention is ***not*** the soft and hard tissues that are exposed to the method; rather, the nature of the invention is biological adhesive materials. The following discussion will explain applicants' position.

Guidance on interpreting the "nature of the invention" *Wands* factor is set forth at MPEP § 2164.05(a). There, it explains that the nature of the invention, i.e., the subject matter to which the claimed invention pertains, is the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art (MPEP, 8th ed., Rev. Feb. 1, 2003, p. 2100-184). The MPEP explains that the pertinent art should be defined in terms of the *problem to be solved* rather than in terms of the technology area, industry, trade, etc. for which the invention is used (page 2100-185, ¶ 2).

In the instant case, the problem to be solved is the augmentation of soft or hard tissue within a mammalian body by using biological adhesive materials that are biocompatible, synthetic, and nonimmunogenic.

With the nature of the invention properly identified, the references cited in the IDS and the specification demonstrate that at the time of the invention, those of ordinary skill in the art of biological adhesive materials had not augmented soft and hard tissue by providing a first crosslinkable component having m nucleophilic groups, wherein $m \geq 2$; providing a second crosslinkable component having n electrophilic groups capable of reaction with the m nucleophilic groups to form covalent bonds, wherein $n \geq 2$ and $m + n \geq 5$; applying the first and second crosslinkable components to the tissue; and allowing the first and second crosslinkable components to crosslink *in situ*.

In view of the foregoing, applicants submit that the nature of the invention is biological adhesive materials and as will be explained *infra*, the use of the biological adhesive materials as recited in claims 1-68 clearly are fully enabled by the disclosure in the specification.

THE STATE OF THE PRIOR ART

Having mischaracterized the nature of the invention, the Examiner's analysis for the state and predictability of the art also suffers. At the paragraph bridging pages 3 and 4 of the Office Action under reply, the Examiner describes the state of the art as directed to the screening of candidate drugs for the treatment of soft and hard tissue and in so doing, asserts that because the pharmaceutical arts are unpredictable, the claimed invention is not enabled.

Because the state of the art and the predictability of the art are really two different *Wands* factors, the two concepts will be analyzed in succession.

As will be explained in detail *infra*, the state of the art is used to determine the amount of detail that must be provided in the specification in order for it to be enabling; state of the art that is contradictory to a claimed invention will only render an invention non-enabling if the application fails to provide enough detail to overcome the deficiencies in the prior art.

Guidance for interpreting the nature of the art is set forth at MPEP § 2164.05(a) where it is explained that the state of the prior art is what one skilled in the art would have known at the time the application was filed about the subject matter to which the claimed invention pertains. MPEP § 2164.05(a), p. 2100-184, col. 2, ¶ 2. The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. MPEP § 2164.05(a), p. 2100-184, col. 2, ¶ 3. The state of the prior art is also related to the need for working examples in the specification. *Id.* MPEP § 2164.03 explains that the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. MPEP § 2164.03, p. 2100-182, col. 1, ¶ 1. Thus, when a great deal is known in the prior art about the nature of the invention and the invention is in a predictable art, then less information on how to make and use the invention is required in the specification. *Id.* By contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, then in order for the specification to be enabling, it must disclose more detail on how to make and use the invention. *Id.*

A review of the specification (pages 1-2) of the instant application and the art cited in the IDSs that are of record show that quite a lot of research has been undertaken relating to biological adhesive materials. In view of the foregoing and with respect to enablement, the specification of the instant application need not disclose an inordinate amount of detail on how to make and use the invention.

Notwithstanding the foregoing, the specification does disclose eight background references (p.2); a detailed discussion of the chemical reactions that the two components of the invention undergo (pp. 6-7); a discussion of synthetic polymers with multiple nucleophilic groups (pp. 8-10); a discussion of synthetic polymers with electrophilic groups (p.10); a discussion of hydrophilic polymers (pp. 10-12); a discussion of hydrophilic polymers (pp. 12-13); a discussion of derivatization of polymers to contain functional groups (p.13); a discussion of preparation of crosslinked polymer compositions (pp. 13-15); a discussion of the incorporation of other components into the crosslinked synthetic polymers (pp.15-18); a discussion of administration of the crosslinked synthetic polymer compositions (pp. 18-19); a discussion of the use of the crosslinked synthetic polymers to deliver charged compounds (p.19); a discussion of the use of the crosslinked synthetic polymers to deliver biologically active agents (pp. 20-21); a discussion of the use of the crosslinked synthetic polymers to deliver cells or genes (pp. 22-24); a discussion of the use of the crosslinked synthetic polymers in ophthalmic applications (p.24); a discussion of the use of the crosslinked synthetic polymer compositions in tissue augmentation (pp.24-25); a discussion of the use of the crosslinked synthetic polymer compositions to prevent adhesions (p.25); a discussion of the use of the crosslinked synthetic polymers to coat implants (p.26); a discussion of the use of the crosslinked synthetic polymers to treat aneurism (p.26); a discussion of other uses for the crosslinked synthetic polymers (pp.26-27); seven examples (pp. 27-34); and 18 figures with related discussions pertaining to each.

In keeping with the requirements of the prior art *Wands* factor, the applicants have provided a disclosure that would satisfy even the most obscure state of the art. Because the state of the art of biological adhesive materials has been previously explored, applicants submit that the ordinary artisan would readily be able to make and use the invention of claims 1-68 by reading through the detailed specification.

THE PREDICTABILITY OF THE PRIOR ART

Having mischaracterized the nature of the invention and the state of the art, the Examiner's analysis for the predictability of the art also suffers.

As will be explained *infra*, the unpredictability *Wands* factor relates to the number of species that must be disclosed in an application in order for a claim to be enabled.

MPEP § 2164.03 explains that the "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. MPEP § 2164.03, p. 2100-182, col. 1, ¶ 2. In other words, if one skilled in the art can readily anticipate the effect of a change within the subject matter (such as a newly found species) to which the claimed invention pertains, then there is predictability in the art. *Id.* By contrast, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then

there is a lack of predictability in the art. *Id.* With respect to the amount of disclosure required in an unpredictable art, the MPEP notes that even in unpredictable arts, a disclosure of every operable species is not required, but more than one will usually be necessary. MPEP § 2164.03, p. 2100-182, col. 2, ¶ 2.

In the instant case, applicants disclose many crosslinkable components having nucleophilic groups (paragraphs 0077-0083) and electrophilic groups (paragraphs 0084-0087). As explained in the response filed on June 21, 2006, the Examples provide several examples of the synthetic polymers having m nucleophilic groups with $m \geq 2$ and n electrophilc groups with $n \geq 2$ (see the table at page 10 of the response). Accordingly, even assuming *arguendo* that the art of biological adhesive materials were an unpredictable art, the disclosure in the specification describing the nucleophilic and electrophilic groups of the present invention would serve to fully enable the invention as recited in claims 1-68 even in view of any unpredictability inherent in the art of biological adhesive materials.

THE QUANTITY OF EXPERIMENTATION:

The Examiner contends that the practice of the claimed invention requires undue experimentation because one of ordinary skill in the art would need to determine the type of soft and hard tissue to be treated (Office Action, page 4). As with the previous *Wands* factors, the Examiner's undue experimentation argument suffers from the mischaracterization of the nature of the invention.

At MPEP § 2164.06, the MPEP quotes the following statement from *In re Colianni*: "An extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." MPEP § 2164.06, quoting, *In re Colianni,* 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977).

As set forth in the discussions of the state and unpredictability of the art, the specification of the instant application provides a great deal of backgrounds, direction, guidance, and examples such that one of ordinary skill in the art would be able to make and use the invention without undue experimentation. In view of the foregoing, applicants submit that the specification enables the practice of claims 1-68 without undue experimentation.

THE BREADTH OF THE CLAIMS:

For the breadth of the claims *Wands* factor, the Examiner states that claims 1-68 are extremely broad due to the vast number of possible augmentation of soft and hard tissues encompassed by the instant invention (Office Action, page 4). Again, the Examiner's breadth of the claims argument suffers from the mischaracterization of the nature of the invention.

Turning again to the MPEP for guidance on what the Federal Circuit expects from the breadth of the claims *Wands* factor, the MPEP at section 2164.08 explains that when analyzing the enabling scope of a claim, the teachings of the specification must not be ignored because claims are to be given their

broadest reasonable interpretation consistent with the specification. To illustrate the importance of this requirement, the MPEP quotes the following statement from *In re Goffe,* 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976):

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts. MPEP § 2164.08, p. 2100-191, col. 2, ¶ 1.

With respect to the issue of undisclosed species, this issue primarily comes into play when an inventor is claiming a new species of plant, animal etc. for which the ordinary artisan would have no knowledge prior to the disclosure in the patent document at issue. Referring to the example given in the MPEP at section 2164.08, in *Amgen v. Chugai,* the Federal Circuit held that Amgen could not generically claim all analogs of the newly cloned EPO gene because only a few EPO genes were disclosed in the Amgen patent and there might be other genetic sequences that code for EPO-type products. MPEP § 2164.08, p. 2100-192, col. 1, ¶ 1, citing, *Amgen v. Chugai Pharmaceutical Co.,* 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied,* 502 U.S. 856 (1991).

In the instant case, applicants are claiming a method for augmenting soft or hard tissue within a mammalian body by applying a first and a second crosslinkable component to the tissue and allowing the first and second crosslinkable components to crosslink *in situ.*

Because the claims limit the crosslinkable components to a first crosslinkable component with m nucleophilic groups wherein $m \geq 2$ and a second crosslinkable component with n electrophilic groups wherein $n \geq 2$ and the specification provides detailed discussions and examples of the claimed crosslinkable components and how they react with each other, it is difficult to argue that the breadth of claims 1-68 is overly broad; accordingly, applicants submit that the breadth of claims 1-68 is fully enabled by the disclosure in the specification.

***WANDS* FACTOR CONCLUSION**

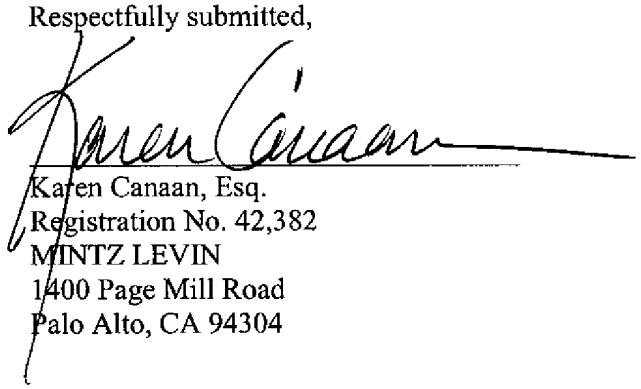
The foregoing analysis demonstrates that the invention as recited in claims 1-68 meets all of the *Wands* factors identified as an issue by the Examiner. Because claims 1-68 are fully enabled by the disclosure in the specification, applicants respectfully request withdrawal of this rejection.

CONCLUSION

With this paper, the Examiner's enablement rejection has been fully addressed and overcome. Because there will be no outstanding issues for this matter upon entry of this paper, applicants respectfully request withdrawal of the outstanding enablement claim rejection and passage of this application to issue.

Any questions regarding this paper or the application in general may be addressed to the undersigned attorney at 650-251-7713 or kcanaan@mintz.com.

Respectfully submitted,

By: 

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